IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF TEXAS
TYLER DIVISION

R.J. REYNOLDS TOBACCO COMPANY; SANTA FE NATURAL TOBACCO COMPANY, INC.; ITG BRANDS, LLC; LIGGETT GROUP LLC; NEOCOM, INC.; RANGILA ENTERPRISES INC.; RANGILA LLC; SAHIL ISMAIL, INC.; and IS LIKE YOU INC.; *Plaintiffs*, *v.* UNITED STATES FOOD AND DRUG ADMINISTRATION; UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES; STEPHEN M. HAHN, in his official capacity as Commissioner of the United States Food and Drug Administration; and ALEX M. AZAR II, in his official capacity as Secretary of the United States Department of Health and Human Services; *Defendants.*	CIVIL ACTION NO. 6:20-cv-00176

PLAINTIFFS' COMBINED REPLY IN SUPPORT OF THEIR MOTION FOR SUMMARY JUDGMENT AND A PRELIMINARY INJUNCTION AND RESPONSE TO DEFENDANTS' CROSS-MOTION FOR SUMMARY JUDGMENT

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INTRODUCTION

In 2012, the D.C. Circuit struck down the first version of the graphic warnings rule, noting that the government had not provided a "shred of evidence" that it would reduce smoking. *R.J. Reynolds Tobacco Co. v. FDA*, 696 F.3d 1205, 1219 (D.C. Cir. 2012), *overruled in part by Am. Meat Inst. v. U.S. Dep't of Agric.*, 760 F.3d 18 (D.C. Cir. 2014) (en banc). The government has now issued a second version of the rule—requiring similarly grotesque warnings—but it no longer even asserts that the warnings would have any positive public health impact. The government's inability to defend the rule on those grounds has locked it into a series of extreme and contrived positions, as its summary judgment brief amply illustrates.

Lacking evidence to support any other justification, the government asserts that it is entitled to commandeer private speech based on a *purely informational* interest. In other words, the government need not demonstrate that the compelled disclosure will have *any* impact on real-world behavior or public health outcomes; nor does it need to tie the compelled disclosure to the correction of a deceptive message.

In its view, the information does not even have to be *important* in any respect. Because the government could not prove its original intended purpose—reducing smoking—it now asks the Court to credit its newly constructed "informational" purpose of allowing consumers to meaningfully evaluate whether to smoke. But in its view, it need not show that its warning has any economic value to the recipient; that it is otherwise important or material to the recipient's decision whether to smoke; or even that the government has ever treated the information as significant. Nor does the government have to make any serious showing that the thrust of the information is unfamiliar to the public. Even though its *own* study demonstrates that 99.5% of individuals already believe that smoking is harmful, the government says it is free to compel whatever more granular messages it wishes, so long as the specific information imparted is in some sense "new." And the Court is expected to simply defer to the agency's judgment on those subjects—even though First Amendment rights are at stake.

In addition, the compelled disclosure can include large, grotesque, and shocking photorealistic images. As long as the government asserts that they are medically accurate, these images can be as

disturbing and controversial as the government wants to make them. And although such images are inherently subject to multiple interpretations, the government need not provide any evidence that the public will interpret the images correctly, or indeed determine what messages the graphic warnings are actually sending and whether they are accurate.

Nor is it necessary for the government to test alternatives, such as public information campaigns that it has championed as successful. It is not necessary even to test less-intrusive warnings, such as text-only warnings, even when there is record evidence that they would perform just as well. Instead, the government can make compelling speech its first resort and make the warnings it compels as obtrusive as it wants—indeed, the size and obtrusiveness of the warnings are not, according to the government, even a question "of constitutional dimension." Opp. 42 (citation omitted).

Putting these contentions together, the government's bottom line is genuinely startling. The government believes it could require any product or advertisement to include large, disturbing, and misleading graphic warnings in the service of "informing" the public of the government's messages. No product or advertisement would be safe—because the government could always pick a more granular piece of information to convey, whatever the public already understands about the subject. And these rules could not be confined to cigarettes; while the government dedicates much of its brief to vilifying cigarette manufacturers, the First Amendment contains no carve-out for disfavored products or unpopular messages. *See, e.g., Sorrell v. IMS Health Inc.*, 564 U.S. 552, 577-78 (2011).

In short, the government's approach would render the First Amendment a dead letter in the context of compelling businesses' speech. Fortunately, the government is wrong about each proposition listed above. And it would have to be right about *all* of them for the Rule to be upheld against First Amendment challenge.

The Rule is equally flawed under the Administrative Procedure Act ("APA"). FDA acted arbitrarily and capriciously in several respects—including by relying on inadequate studies, conducting a deficient cost-benefit analysis, failing to consider alternative approaches, and refusing to respond meaningfully to comments (or even to criticisms from peer reviewers). FDA also deprived the public

of notice and a meaningful opportunity to comment by withholding some crucial data altogether and giving the public only fifteen days to comment on its qualitative studies.

For these reasons—and all the additional reasons discussed below and in the opening brief—Plaintiffs' motions for summary judgment and a preliminary injunction should be granted, and Defendants' cross-motion for summary judgment should be denied.

ARGUMENT

I. PLAINTIFFS ARE ENTITLED TO SUMMARY JUDGMENT ON THEIR CLAIMS.

A. The Rule Violates The First Amendment.

The government attempts to load the dice (at 15-17) by mischaracterizing the applicable standard of review and suggesting that its fact-finding is entitled to deference even with respect to Plaintiffs' First Amendment claim. This is incorrect. Courts have made crystal clear that the burden is on the *government* to demonstrate that the Rule complies with the First Amendment. *See Zauderer v. Office of Disciplinary Counsel of Supreme Court of Ohio*, 471 U.S. 626, 647 (1985) (explaining that "the burden is on the State to present a substantial governmental interest justifying the restriction as applied to appellant and to demonstrate that the restriction vindicates that interest through the least restrictive available means"); *Ibanez v. Fla. Dep't of Bus. & Prof'l Reg.*, 512 U.S. 136, 146 (1994); *Edenfield v. Fane*, 507 U.S. 761, 770 (1993); *NIFLA v. Becerra*, 138 S. Ct. 2361, 2377 (2018).

Moreover, contrary to the government's plea for deference, the Rule must be reviewed de novo. The Fifth Circuit has explained that agency actions do not receive "the usual deference when reviewing a potential violation of a constitutional right" and "courts should make an independent assessment." *Tex. Office of Pub. Util. Counsel v. FCC*, 183 F.3d 393, 410 (5th Cir. 1999) (citation omitted); *see also Porter v. Califano*, 592 F.2d 770, 780 (5th Cir. 1979) (concluding it "would be error" for a district court to "rel[y] on agency findings or defer[ ] to agency rulings" in deciding a First Amendment claim); *Exxon Mobil Corp. v. Mnuchin*, 430 F. Supp. 3d 220, 228-29 (N.D. Tex. 2019).[1]

[1] *See also, e.g.*, *Bruce Packing Co., Inc. v. NLRB*, 795 F.3d 18, 22 (D.C. Cir. 2015) ("[W]e 'owe[ ] no deference to the [Board's] pronouncement on a constitutional question,' leaving us to review the due process claim de novo."); Martin H. Redish & William D. Gohl, *The Wandering Doctrine of*

Porter explained that these principles follow both from the plain language of the APA and from the broader logic of constitutional litigation. The Fifth Circuit declared that "[t]he intent of Congress in 5 U.S.C. § 706(2)(B) was that courts should make an independent assessment of a citizen's claim of constitutional right when reviewing agency decision-making." 592 F.2d at 780. "Whereas § 706(2) authorizes reviewing courts to overturn agency findings and actions involving *non-constitutional* claims only when the agency has abused its discretion, § 706(2)(A), acted arbitrarily and capriciously, § 706(2)(A), or made findings unsupported by substantial evidence, § 706(2)(E), section 706(2)(B) explicitly authorizes the court to set aside any agency action 'contrary to constitutional right.'" *Id.*

Porter also explained that this "literal reading of § 706(2)(B)" comports with "general principles of constitutional adjudication," which require "an independent examination of the record [to] be made in order that the controlling legal principles may be applied to *the actual facts* of the case." *Id.* at 781 (internal quotation marks omitted and emphasis added). And this is especially true "in the First Amendment area," because "courts, not agencies, are expert on the First Amendment." *Id.* at 780 n.15; *see* 33 Wright & Miller, Federal Practice & Procedure § 8404 (2d ed.) ("De novo review of 'constitutional' [facts] . . . persists . . . especially in First Amendment litigation.").

The government strains to distinguish *Porter* by pointing to irrelevant aspects of that case, such as the plaintiff's statutory right to an evidentiary hearing. Opp. 16 n.7.[2] But the Court's discussion of Section 706(2)(B) stands alone and speaks for itself. It is Fifth Circuit law, then, that deferring to "agency findings" in a constitutional case is error. *Porter*, 592 F.2d at 780.

Accordingly, Defendants' reliance (at 16) on out-of-circuit authorities is unavailing.[3] And their

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Constitutional Fact, 59 ARIZ. L. REV. 289, 326-27 (2017); *cf. Bose Corp. v. Consumers Union of U.S., Inc.*, 466 U.S. 485, 499 (1984) (appellate courts must "'make an independent examination of the whole record' in order to make sure that 'the judgment does not constitute a forbidden intrusion on the field of free expression'" (quoting *New York Times Co. v. Sullivan*, 376 U.S. 254, 284-286 (1964))).

[2] This brief refers to Plaintiffs' motion for summary judgment and a preliminary injunction as "Mot." and to Defendants' combined cross-motion for summary judgment and opposition as "Opp."

[3] Of course, even applying a more deferential approach, the D.C. Circuit refused to adopt FDA's "flawed" conclusions in the first rulemaking. *R.J. Reynolds*, 696 F.3d at 1220; *see id.* at 1221 n.15 (declining to defer to Congress's judgment regarding the efficacy of the warnings because there was

reference to *Trump v. Hawaii* misses the mark, as that decision stands only for the proposition that courts give "appropriate weight" to the Executive's assessment of the facts, "particularly in the context of litigation involving 'sensitive and weighty interests of national security and foreign affairs.'" 138 S. Ct. 2392, 2422 (2018) (internal quotation marks omitted). In short, Defendants are not entitled to hide behind deference. They must carry the burden of justifying their imposition on Plaintiffs' speech, and they must do so on de novo review.

1. *Zauderer* does not apply.

(a) The warnings are not reasonably related to "consumer deception."

i. As the opening brief explained (at 20-21), *Zauderer* itself makes clear that it applies only in the context of preventing deception of consumers. In that unique context, where the underlying commercial speech has little if any constitutional worth and compelled corrective speech will logically advance the substantial government interest in preventing consumer deception, it was sensible for the Supreme Court to determine that compelled corrective speech will be upheld if purely factual and uncontroversial, reasonably related to the interest in preventing consumer deception, and neither unjustified nor unduly burdensome. *See Zauderer*, 471 U.S. at 651. But there is no logical basis for applying any standard of review less strict than *Central Hudson* to laws that regulate lawful and non-misleading speech: Regardless of whether a regulation restricts speech or compels a disclosure, the government cannot regulate such speech unless its regulation can withstand heightened scrutiny. *See, e.g.*, *Cent. Hudson Gas & Elec. Corp. v. Pub. Serv. Comm'n*, 447 U.S. 557, 564-66 (1980). For that reason, the Court has specified that an "essential feature[]" of the disclosures in *Zauderer* was that they were aimed at "inherently misleading commercial advertisements," *Milavetz, Gallop & Milavetz, P.A. v. United States*, 559 U.S. 229, 250 (2010), and repeatedly explained that, to qualify for *Zauderer* review, a required disclosure must be "an appropriately tailored check *against deception or confusion*," *Ibanez*, 512 U.S. at 146 (emphasis added). As the government does not dispute, the Supreme Court has never held that

"little evidence showing that the graphic warnings will advance the stated purpose of the statute"). As detailed below, FDA's second effort would similarly fail even under a more lenient standard.

Zauderer applies outside of the context of correcting consumer deception. And several individual justices have even more explicitly noted that *Zauderer* is limited to laws aimed at preventing consumers from being deceived by misleading or potentially misleading commercial speech. Mot. 21 n.9.

The Supreme Court's decision in *United States v. United Foods, Inc.* is also instructive. 533 U.S. 405 (2001). *United Foods* considered a scheme requiring mushroom handlers to fund advertisements. The Court evaluated and struck down the scheme under heightened scrutiny, and noted that this approach was "not inconsistent" with *Zauderer* because there was "no suggestion" that the "assessments [at issue] are somehow necessary to make voluntary advertisements nonmisleading for consumers." *Id.* at 416. Defendants dismiss *United Foods* (at 20) because it arose in the purportedly unrelated context of compelled financial contributions. But their argument is with the Court, which chose to distinguish *Zauderer* in a way that underscored once again that consumer deception is an essential prerequisite of the *Zauderer* test. Nor is it any surprise that *United Foods* treated *Zauderer* as relevant, because compelled financial contributions raise similar First Amendment issues to compelled disclosures. *Cf. Janus v. Am. Fed'n of State, Cnty., & Mun. Emps., Council 31*, 138 S. Ct. 2448, 2460 (2018).

Fifth Circuit precedent, too, indicates that *Zauderer* is directed at consumer deception. The Fifth Circuit has expressly stated that the Supreme Court created the *Zauderer* standard "to gauge" regulations that "are directed at deceptive or misleading commercial speech and require a disclosure." *Test Masters Educ. Servs., Inc. v. Robin Singh Educ. Servs., Inc.*, 799 F.3d 437, 453 (5th Cir. 2015); *see also Cent. Ill. Light Co. v. Citizens Util. Bd.*, 827 F.2d 1169, 1173 (7th Cir. 1987) (similar); *Dwyer v. Cappell*, 762 F.3d 275, 282 (3d Cir. 2014) (similar). And the Fifth Circuit has acted on this view, repeatedly applying heightened scrutiny rather than *Zauderer* in analyzing compelled disclosures that were not related to preventing consumer deception. *See Allstate Ins. Co. v. Abbott*, 495 F.3d 151, 164-65 (5th Cir. 2007); *Hersh v. U.S. ex rel. Mukasey*, 553 F.3d 743, 764-68 (5th Cir. 2008).

Defendants try to distinguish *Allstate* (at 20) by suggesting that it pertained only to an attempt to *restrict* speech. This is simply incorrect. One of the regulations considered in *Allstate* provided that an insurer could recommend its affiliated repair facilities *only* if it also recommended other repair facilities. 495 F.3d at 165. This is directly analogous to the compelled speech at issue here: the Rule

provides that Plaintiffs can sell or advertise cigarettes *only* if they include the graphic warnings.[4] The government's discussion of *Hersh* is similarly off-base. The fact that the Fifth Circuit did not even consider applying *Zauderer* in a case concerning the compelled disclosure "of certain basic information regarding bankruptcy proceedings" is a strong indication that *Zauderer* does not apply in contexts that are unrelated to consumer deception. *See* 553 F.3d at 764-68.

In light of those Supreme Court and Fifth Circuit authorities, the government's citations to decisions from other circuits are unpersuasive, and its parade of horribles is also off-base. Defendants worry about routine warning labels and ingredient lists. But many such disclosures can be justified by reference to consumer deception, and others would be able to survive heightened scrutiny. At most, this is an argument that *Central Hudson*, rather than strict scrutiny, should apply to the warnings. The government's position, by contrast, is troubling because it violates the basic logic of *Zauderer*: that truthful commercial speech gets more constitutional protection than *misleading* commercial speech.

ii. The government also half-heartedly suggests (at 20-21) that these warnings *are* related to consumer deception. But it ignores the opening brief's arguments on this point. Mot. 21-22.

First, the commercial speech *at issue* must be deceptive or misleading. *See Test Masters*, 799 F.3d at 453 (referring to disclosures "directed at deceptive or misleading commercial speech"); *Milavetz*, 559 U.S. at 250 (*Zauderer* permitted disclosures that were "intended to combat" "misleading commercial advertisements"). Any other rule would be unworkable. Under the government's logic—which would extend *Zauderer* to disclosures in commercial speech that is not itself misleading—the government could just as easily require these warnings to be included on non-cigarette and non-tobacco products and advertisements. And here, it is undisputed that the commercial speech at issue is non-deceptive and non-misleading. Indeed, as Defendants do not and cannot dispute, Plaintiffs are *prohibited by law*

[4] The government tries (at 20 n.10) to make something of the fact that a certiorari petition citing *Allstate* was denied. "But '[t]he significance of a denial of a petition for certiorari ought no longer . . . require discussion. This Court has said again and again and again that such a denial has no legal significance whatever bearing on the merits of the claim.'" *Ramos v. Louisiana*, 140 S. Ct. 1390, 1404 n.56 (2020) (quoting *Darr v. Burford*, 339 U.S. 200, 226 (1950) (Frankfurter, J., dissenting)).

from making false or misleading claims through cigarette packages and advertising. Mot. 20-21.[5]

Second, the government has made no effort to show that the public remains misled by *any* historical representations by cigarette manufacturers, let alone that it remains misled by any misrepresentations concerning *the subject matter of these warnings*. And third, the rule governs *all* of the Plaintiffs—the retailers as well as the manufacturers. And there is no suggestion that the Retailer Plaintiffs *ever* engaged in any deceptive speech relating to cigarettes. In short, it is unsurprising that the Rule's own stated goal is to "promote greater public understanding," not to prevent consumer deception. 85 Fed. Reg. at 15,668. *Zauderer* does not apply here.

(b) The warnings are not "purely factual."

The warnings also should not be reviewed under *Zauderer* because they are not purely factual. Mot. 22-25. First, photorealistic images are inherently subject to multiple interpretations. This was illustrated in the government's own study when respondents could not figure out the meaning of the "erectile dysfunction" and "crying baby" images, among others. Mot. 28 (early versions of the "Sick Child," "Diseased Feet," "Cataracts," and "Open Heart Surgery" images scored "low" on "clarity of message," and the early versions of the "Neck Tumor," "Crying Baby," and "Finger Prick" images rated only "medium" on clarity of message or image); *see also* Second Appendix ("Second App.") (collecting quotations from the transcript excerpts in the administrative record, which reflect the confusing, misleading, and ambiguous nature of the images); Appendix to Motion ("App."). At a minimum, the government would have to make a record-based showing that each image conveys solely an unambiguous, factually correct meaning, which it has not even *attempted* to do here.[6]

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[5] The amici States (at 11-12) argue that the current packaging and advertisements must be evaluated in light of decades-old alleged behavior, citing *Warner-Lambert Co. v. FTC*, 562 F.2d 749, 769 (D.C. Cir. 1977). This precise argument was rejected by the D.C. Circuit in *R.J. Reynolds*. As the D.C. Circuit explained, the compelled disclosure in *Warner-Lambert* was "a remedial measure designed to counteract specific deceptive claims" that Listerine would help prevent or alleviate colds. 696 F.3d at 1215-16; *see id.* (noting that the "states' argument overlooks the broader context of [*Warner-Lambert*]").

[6] Contrary to Defendants' insinuation (at 28), *Zauderer* did not endorse the use of illustrations in government-mandated disclosures. Instead, *Zauderer* addressed a government *prohibition* of illustrations in advertisements. 471 U.S. at 647. In any event, the Court simply observed that

The government's response is feeble. It does not dispute the underlying premise that photorealistic images are inherently ill-suited to communicating a factual message, but suggests (at 28) that any confusion caused by the images is fixed by the accompanying text, because the "obvious" meaning of each image *is* "the warning statement with which they are paired." To begin, this is purely speculative. FDA did not test this proposition—for example, by designing its quantitative studies to determine what meanings consumers took from the final image-text pairs and whether those meanings were indisputably accurate—and the bare assertion by government counsel should carry no weight.[7] Furthermore, the third qualitative study actually proves otherwise. In that study, some respondents indicated that they were confused and misled even by warnings that combined images and text. *See* Second App. 6 ("the picture is still confusing"); *id.* at 15 ("this is way confusing"); *id.* ("a little exaggerated"); *id.* at 20 ("It's confusing."); *id. passim* (reflecting that even the image-text *pairings* conveyed a host of misleading and inaccurate messages to consumers). It is also worth noting that, in *R.J. Reynolds*, the D.C. Circuit had no trouble finding the images subject to misinterpretation even though they were paired with textual warnings. 696 F.3d at 1216. Moreover, this argument flies in the face of the government's own position that large graphic warnings are necessary in light of "the wide variability in the general public's ability to read and understand health information." Opp. 45. Obviously, members of the public who cannot *read or understand* the textual warnings also cannot interpret the graphic warnings in light of them. And in any event, misleading and inaccurate images cannot be fixed with misleading and inaccurate text. *See infra* p. 15.

And even if the government were correct, its argument would run headfirst into *another* issue identified in the opening brief (at 23): namely, that the very fact that the government added graphic warnings to the textual statements indicates that the graphics are doing something *other* than conveying factual information. Here, the government argues (at 28) that the relevant factual information is

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illustrations serve communicative functions in advertisements and that their use in advertisements is not always misleading. *Id.* at 648-49.

[7] The closest the government came was asking respondents whether the images were "perceived to be understandable." AR 39687. But *perceived* understanding is distinct from *actual* understanding of the particular message FDA intended to convey.

conveyed by the textual statement; the only purpose of the graphics, then, is to make the overall warning striking, frightening, and memorable. And this means that *Zauderer* does not apply. For example, in *R.J. Reynolds*, the D.C. Circuit concluded that the warnings were intended to promote an emotional response in part because the government admitted—just as it does here, 95 Fed. Reg. at 15,655—that the purpose of the images was to make the warnings easier to remember. 696 F.3d at 1216. More generally, it makes little sense for the government to assert that it has a constitutionally sufficient interest in requiring images that are misleading in and of themselves (and therefore require accompanying text). *See* Mot. 26-29.

In any event, the particular warnings at issue here are obviously intended to shock the viewer and to convey the government's ideological message that consumers should not smoke. As documented in the opening brief (at 23-25), respondents in FDA's own qualitative studies recognized this, as did numerous news organizations. *See also* Second App. 4 ("insanely graphic"); *id.* at 8, 19 ("scare tactic"); *id.* at 15 ("It's just shock value."); *id.* at 6 ("Shame, defeat and disgust. That's all I can see in that."). The point was further established by a consumer survey conducted by an expert in survey research, Dr. Samantha Iyengar (which the government's brief does not meaningfully address).[8] That survey showed that large majorities of respondents believed that the warnings were "trying to make people feel afraid," "trying to shock people," and conveyed the message that people "should not smoke" cigarettes. Mot. 24. Notably, the Iyengar survey is far better targeted to address whether the images were shocking and ideological than FDA's quantitative study, which did not study the

[8] Although the government in passing asserts that Dr. Iyengar's survey was "scientifically flawed," it does not elaborate on that assertion (and it is not enough merely to incorporate the Rule by reference, *see infra* p. 14). In any event, FDA's main critique of her survey is that it largely assessed outcomes that "relate to behavior" rather than "public understanding of the negative health consequences of smoking." 85 Fed. Reg. at 15,668. This mischaracterizes Dr. Iyengar's study, which primarily addressed two key questions the government never studied itself: whether the warnings conveyed an emotional message, and whether they did a better job conveying the risks of smoking than less-intrusive alternatives. AR 28007-16; *see infra* p. 26. Having failed to address these issues, the government can hardly hope to carry its burden by raising small-bore technical criticisms of Dr. Iyengar's careful study. *See* 85 Fed. Reg. at 15,668.

messages that consumers understood from the warnings and simply asked respondents a binary question of whether they regarded the warnings as fact or opinion. AR 39707; *see* Opp. 32.[9] But a factually accurate warning can still be intended to shock (for example, a picture of a mutilated animal displayed by an animal-rights activist, Mot. 24). It is especially odd for the government to rely on this measure as the ultimate arbiter of whether a warning is purely factual, given its own view elsewhere in the brief that this measure "ha[s] nothing to do with the actual factual accuracy of the warnings." Opp. 61 (internal quotation marks omitted). And even the FDA study showed that a significant percentage of respondents thought the warnings were opinion rather than fact. For example, only 64% of participants viewed the diabetes warning as factual, only 65.5% viewed the cataracts warning as factual, and only 66% viewed the bladder cancer warning as factual. *See* AR 39723-24.

The government's basic response to all of this (*see* Opp. 32 & n.18) is that (assertedly) medically accurate images should be categorically regarded as factual (except perhaps if there is direct evidence that the government intended them to be shocking or ideological). This would lead to untenable results. All of the hypotheticals suggested by Plaintiffs (at 24)—diseased feet on fast food bags, sick babies on bottles of wine, and mutilated animals on packages of beef—would be permissible.

The government's position also does not make logical or doctrinal sense. Whether or not the images are intended to shock and to convey the government's ideological message is a question that can be evaluated based on the images themselves, not solely by a direct inquiry into subjective government motivation. *See, e.g.*, *R.J. Reynolds*, 696 F.3d at 1216-17 ("These inflammatory images … cannot rationally be viewed as pure attempts to convey information to consumers."). The D.C. Circuit's reasoning is especially powerful here because the two sets of warnings are quite similar and, in fact, some of the images are near parallels of each other:

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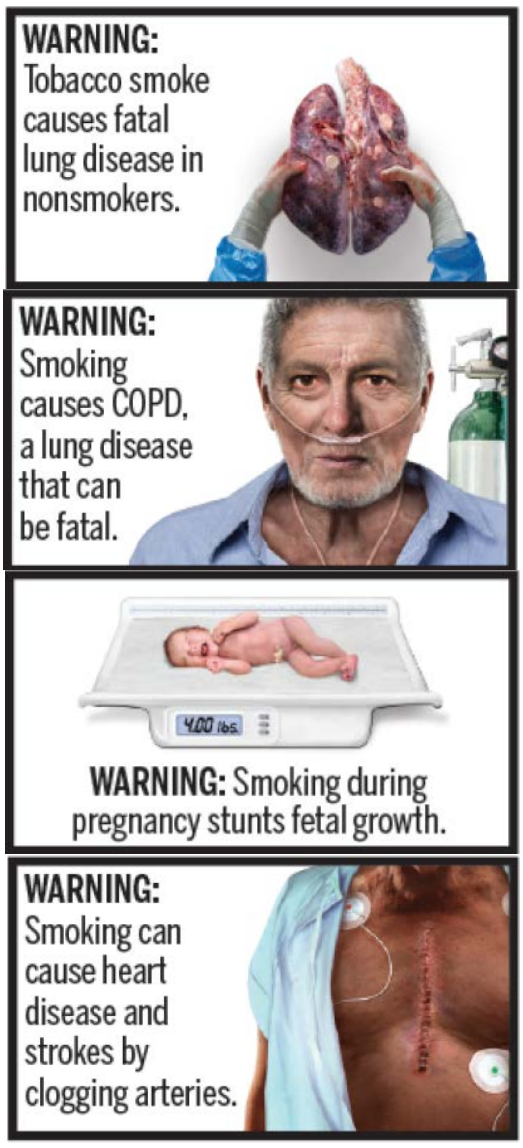
[9] Indeed, the government admits (at 12) that its study was not designed to assess the emotional impact of the warnings. This is inexcusable, especially after respondents in the qualitative studies volunteered that the warnings elicited emotional reactions. The government's failure to examine this issue means it cannot carry its burden to show the warnings comply with the First Amendment; it also means the government violated the APA by failing to consider an important aspect of the problem. *See Motor Vehicle Mfrs. Ass'n of U.S., Inc. v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983).



Indeed, the government seems to understand that just looking at the images is enough to conclude they are intended to provoke an emotional response; that is presumably why it includes only two of them in its 75-page brief.

And notably, even if the government were right, Plaintiffs *have* pointed to direct evidence of its intentions. This evidence shows that the government repeatedly revised the images to make them more frightening and grotesque, as well as more emotionally charged. Mot. 11-12.[10]

[10] The government counters (at 31-32) with a single example of when it *declined* to make an image more disturbing by depicting the sick baby in an incubator. But identifying a single instance of

(c) The warnings are not "uncontroversial."

The warnings are also not entitled to *Zauderer* review because they are controversial. Mot. 25-28. Not only do they convey an ideological message (as shown above), but they are also exaggerated and subject to misinterpretation. Notably, FDA *did not test* whether the warnings conveyed accurate messages. Mot. 27-28. This by itself means that it has not carried its burden. Moreover, the available evidence shows that consumers would misinterpret the warnings.

First, as the opening brief explained (at 26-27), every warning exaggerates the danger of smoking. The government's brief offers a specific defense (at 29-30) of only four of the warnings, and the responses are uniformly unpersuasive:

- FDA has no answer for why it included three cancerous lesions in the "Diseased Non-Smoker's Lungs" image, despite how unusual that would be. *See* AR 28120-21.
- FDA does not explain why the "Diseased Feet" image depicts multiple toes that were amputated at the same time. This would be "uncommon" in types of peripheral vascular disease other than Buerger's disease, AR 28127, Declaration of Robert Wagmeister, MD ¶¶ 3-4, which even Defendants concede (at 30) is "a very rare condition."
- FDA insists that the "Neck Tumor" image is not misleading because it is possible that if an individual were also affected by factors distinct from smoking (such as lack of transportation), that person could have a tumor of that size. Of course, the textual warning does not mention those contributing factors; it only mentions smoking. This makes it misleading. *See* AR 28127.
- The government cannot dispute that it is uncommon for children to be hospitalized due to an asthma attack caused by smoke, and that the "Sick Child" image is therefore a misleading exaggeration. Mot. 26; AR 28112-13. The government instead attempts to sidestep the charge by focusing on the *increase* in the likelihood of hospitalization, rather than the overall likelihood of hospitalization.

The government's defense of the neck tumor image, in particular, is telling, because it only highlights that photorealistic images are subject to multiple interpretations and are poorly suited for delivering a specific factual message. According to Defendants, the neck cancer image is not misleading because a neck tumor of that size would not be "unusual for patients from underserved communities." Opp. 30 (internal quotation marks omitted). But nothing about the image indicates

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a proposed warning that was too disturbing even for FDA is hardly dispositive of the question here. And notably, FDA changed even that image to make the baby appear more distraught, Mot. 11, and then changed it again to make the baby's low birth weight more prominent, 85 Fed. Reg. at 15,677 (despite receiving a comment that this birth weight was misleading, Mot. 27, AR 27495).

that the warning is limited to individuals from underserved communities, and no reasonable viewer would interpret it that way. Thus the government has in effect conceded that the image is misleading.

The government offers no response at all to Plaintiffs' criticisms of the other seven warnings, and instead refers generally to the "more than a dozen full pages of the Federal Register" that "FDA devoted … to defending the accuracy of each individual warning." Opp. 29. But gesturing at arguments is not enough to preserve them. *Cf. Yohey v. Collins*, 985 F.2d 222, 224-25 (5th Cir. 1993).[11] And in any event, the Rule's defense of the warnings is also unpersuasive:

- The "Cataracts" image is misleading because a cataract would have been treated before it progressed to the stage depicted and because it exaggerates the risk of blindness from cataracts in the United States. Mot. 26; AR 28117. Once again, FDA relied on a host of factors distinct from smoking to insist that it would be possible for an individual to experience advanced cataracts as depicted. 85 Fed. Reg. at 15,684. And rather than addressing the fact that blindness occurs in only 0.48% of cataracts patients in the *United States*, Mot. 26, AR 28534, FDA shifted to focus on the percentage of individuals *in North America* whose cataracts caused blindness (13%), 85 Fed. Reg. at 15,684.
- Regarding the "COPD Nasal Cannula" image, FDA failed to show that receiving long-term oxygen was anything other than a "worst case scenario" and did not identify the "proportion of smokers developing COPD who will require long-term oxygen therapy." AR 36098. Instead, FDA addressed how many adults in the U.S. use supplemental oxygen therapy for *any* reason, as well as the percentage of Medicare beneficiaries with COPD (which may or may not have arisen from smoking) that received oxygen therapy. 85 Fed. Reg. at 15,679.
- Regarding the "Crying Baby" image, FDA did not dispute that babies "born to women who smoke cigarettes weigh approximately 200 grams less than infants born to non-smoking women," which means most babies born to smoking women would still weigh more than five pounds. AR 27495, 36097. Indeed, FDA did not even address what the average impact of smoking would be on an infant's birth weight. FDA instead simply noted that maternal smoking increases the risk for a very low birth weight, which is defined as "any weight less than 1,500 grams (which is equivalent to about 3 pounds, 4 ounces)," and concluded that "therefore four pounds is not an 'extremely' low birth weight." 85 Fed. Reg. at 15,677. But the mere fact that there is *some* increase in the risk is not enough to render the warning non-misleading, and FDA provides no information about the degree of additional risk.
- Regarding the "Open Heart Surgery" image, FDA did not dispute that another treatment is "2.5 times more common" than open heart surgery; AR 27495, it simply asserted that open

[11] Imagine for example that Plaintiffs, instead of articulating any criticisms of the warnings in their briefs, simply pointed to the lengthy passages in their comments that examined the warnings. One suspects the government would not have viewed that as an adequate presentation of the arguments.

heart surgery is common enough. 85 Fed. Reg. at 15,677-78.

- Regarding the "Bloody Urine" image, FDA did not specifically respond to the comment that failing to provide information about the relative risk of bladder cancer or the "risk plateau" was misleading. AR 36096; *see* 85 Fed. Reg. 15,675-76.
- Regarding the "Erectile Dysfunction" and "Finger Prick" images, FDA failed to specifically respond to the comment that failing to convey "absolute or relative risk" of erectile dysfunction or diabetes "associated with smoking" was misleading. Mot. at 27; AR 36099-100; *see* 85 Fed. Reg. at 15,680, 15,683.

Indeed, the government's own studies demonstrate that the warnings are controversial. Mot. 28-29; *see* App., *passim* (collecting responses showing that the warnings were confusing, inaccurate, and misleading). This has become even more apparent now that the underlying data has been produced. *See, e.g.*, Second App. 2 ("[I]t's been blown out of proportion. So I would kind of think of it as . . . fake, and you kind of don't take it seriously."); *id.* at 8 ("exaggerated"); *id.* at 18 ("I'm confused."). It is no wonder that the government gave the public only fifteen days to comment on the studies, and never released the underlying transcripts during the rulemaking process. *See infra* pp. 31-33.

It is worth noting that the problem is not limited to the graphic element of the warnings. The textual warnings are likewise misleading, and the government is wrong to claim (at 21) that Plaintiffs "do not actually dispute that all eleven [textual] statements convey purely factual information." Plaintiffs disputed this in several ways, including by pointing to the warnings' location and size, the fact that most of them misleadingly focused on conditions that less frequently arise from smoking as opposed to more prevalent conditions, and the fact the statements conveyed misleading, confusing, or inaccurate messages to study participants, including by their use of the word "cause" (as opposed to more accurate phrases such as "increases the risk of," "may cause," or "can cause"). Mot. 12, 25, 28, 36, 54, 56; AR 23337 (the study's "most prevalent finding" was participants' "negative reaction" to warnings that said smoking "causes" a disease); AR 23292 (similar); *see also* App., *passim* (showing participants thought textual warnings were confusing or misleading); Second App. 8 ("[O]nce again, you don't have any . . . word like 'can' or 'could' or whatever in there. It just says [i]t causes. We'll, it's not true."), *id.* at 20 ("too confusing"); *id.* at 23 ("I just don't like [*c*]*ause*, the word [*c*]*ause*."). The government offers no persuasive response to any of these arguments.

2. Even if the *Zauderer* standard applied, the Rule could not survive constitutional scrutiny.

(a) The Rule is "unjustified" by any constitutionally sufficient purpose.

i. The only interest Defendants assert is promoting public understanding of the risks of smoking. Mot. 30. But as the D.C. Circuit explained in *R.J. Reynolds*, such a "purely informational" interest cannot "stand on its own," and should be viewed solely as "a description of the means by which [FDA] plans to accomplish its goal of reducing smoking rates, and not an independent interest capable of sustaining the Rule." 696 F.3d at 1221. Defendants attempt to distinguish *R.J. Reynolds*, but fail. They suggest (at 23 n.13) that the only problem in *R.J. Reynolds* was the absence of "a barometer" for assessing the rule's effectiveness—which, they claim, they have provided here by choosing their own metrics of success and then satisfying those metrics. This is wrong, because *R.J. Reynolds* also imposed limitations on *what* the barometer could be. As the panel explained, FDA cannot be allowed to "define 'effectiveness' however it sees fit." 696 F.3d at 1221. Such an approach would both turn the "'substantial interest' requirement [into] a complete nullity" and "eviscerate the requirement that any restriction 'directly advance' that interest." *Id.*

In other words, the government cannot simply announce that it has an interest in informing people about erectile dysfunction and then brag that its erectile dysfunction warning directly advances that interest. To satisfy *Zauderer*, it must at minimum show that its approach is effective at achieving a legitimate real-world objective such as "encourag[ing] smokers to quit." *Id.* That is how then-Judge Kavanaugh understood *R.J. Reynolds*, citing it for the proposition that "it is plainly not enough for the Government to say simply that it has a substantial interest in giving consumers information," because such a "circular formulation" would apply to "any and all disclosure requirements." *Am. Meat Inst. v. USDA*, 760 F.3d 18, 31-32 (D.C. Cir. 2014) (en banc) (Kavanaugh, J. concurring).

The government attempts (at 20-21) to defend this interest by hiding behind congressional determinations. But Congress cannot redefine the parameters of what is constitutional. It is the courts' role to delineate what *sorts* of harm can justify an imposition on the free speech rights of private entities. In any event, as the D.C. Circuit recently noted, "the Tobacco Control Act … expresses a

consistent concern for reducing smoking." *Cigar Ass'n of Am. v. FDA*, 964 F.3d 56, 62 (D.C. Cir. 2020). Given Congress's fundamental concern with reducing smoking rates, there is little reason to believe that it was committed to the goal of providing information about smoking just for information's sake. Indeed, in its *first* graphic warnings rule, FDA appropriately focused on Congress's interest in reducing smoking; FDA abandoned that position only after its own studies showed that the graphic warnings would not have that effect. *See R.J. Reynolds*, 696 F.3d at 1219-20. And FDA's reliance on congressional choices rings especially hollow, given that the text of most of the warnings, and the images for *all* of the warnings, were chosen by FDA rather than Congress.

The various other authorities that Defendants cite for the sufficiency of an interest in promoting public understanding without more are distinguishable or unpersuasive. Most of the cases they cite discuss either an interest in preventing consumer deception or an interest in affecting real-world behavior, not a purely informational interest. *See Milavetz*, 559 U.S. at 252-53 ("[Government's] interest in preventing deception of consumers" (citation omitted)); *Citizens United v. Fed. Election Comm'n*, 558 U.S. 310, 368-69 (2010) (the disclaimer "avoid[s] confusion by making clear that the ads are not funded by a candidate or political party"); *id.* at 371 ("[the] disclosure permits citizens and shareholders to *react* to the speech of corporate entities in a proper way" (emphasis added)); *Zauderer*, 471 U.S. at 65 ("the State's interest in preventing deception of consumers"); *Pub. Citizen Inc. v. La. Attorney Disciplinary Bd.*, 632 F.3d 212, 220 (5th Cir. 2011) ("two substantial government interests: protecting the public from unethical and potentially misleading lawyer advertising and preserving the ethical integrity of the legal profession"); *Am. Hosp. Ass'n v. Azar*, No. 1:19-CV-03619 (CJN), 2020 WL 3429774, at *17-18 (D.D.C. June 23, 2020) ("the agency's asserted interest of bringing down health care costs" with "price transparency"); *Nicopure Labs, LLC v. FDA*, 944 F.3d 267, 284 (D.C. Cir. 2019) ("substantial interest in ensuring that any modified risk statements are accurate and nonmisleading"); *Disc. Tobacco City & Lottery, Inc. v. United States*, 674 F.3d 509, 520, 562 (6th Cir. 2012) (asking whether the warnings "are reasonably related to the purpose of preventing consumer deception" and also noting "a significant interest in preventing juvenile smoking"). And while the district court's opinion in *Cigar Association* did endorse a purely informational interest, the D.C. Circuit

reversed that decision on other grounds (without reaching the First Amendment issues). 964 F.3d at 64-65.

ii. But even if the government's purely informational interest were sufficient (which it is not), it is not implicated here because the public "already know[s]" the dangers of smoking. *NIFLA*, 138 S. Ct. at 2377. As the opening brief explained (at 30-31), the public is overwhelmingly aware that smoking is harmful, and it also knows about the major risks of smoking (indeed, FDA has *conceded* that the public has a high level of knowledge about the risks addressed by the TCA's textual warnings).[12]

It may seem obvious that the major risks of smoking are well known. Indeed, one of the studies the government cites acknowledged that "most people today recognize major health risks from smoking," AR 05875, and even the government itself refers to the "oft-repeated" fact that smoking is the leading cause of preventable death in the United States, Opp. 1.[13] The government nevertheless attempts to dispute this point, but its responses are lacking.

First, the government attacks the report of Professor Klick, who used the Population Assessment of Tobacco and Heath ("PATH") study data and other public surveys to show that the risks of smoking are widely known. AR 27897-903. But the only relevant criticism the government mentions (at 25) is that Professor Klick purportedly failed to describe his methodology with respect to his use of "PATH data for specific health outcomes." This is wrong. Professor Klick clearly

[12] The government disputes (at 24) that it has made such a concession, but does not actually engage with the opening brief's argument on this point. Mot. 31-32. Moreover, the government's only response on the merits is that for one of the TCA's warnings, slightly over 40 percent of respondents in its study characterized it as providing "new information." Opp. 25. Even setting aside the many methodological problems with the study, *see infra* p. 22, the "new information" question at best indicates that the respondent believes she received *some* new information, without specifying *what* that information was. (For example, for the oxygen therapy image, the new information could have been what an oxygen mask looks like.) Accordingly, it is unpersuasive to suggest (as the government repeatedly does) that this measure can demonstrate whether respondents *actually* learned the information intended to be conveyed by the warnings.

[13] Moreover, "youth and adult smoking rates are at historic lows," and the number of adolescents who smoked cigarettes fell to 2.7% in 2018. AR 27482. Accordingly, while the government's brief may create the impression (at 6) that cigarette smoking is growing among youths, any such suggestion would be incorrect.

explained his methodology, which simply combined data from different waves of *FDA's own* PATH study to show that most adults know that smoking can cause the specific consequences in the graphic warnings. AR 27909-15; *see* AR 27897 (explaining that Professor Klick derived the average perception of smoking harm across the three publicly available waves of FDA's PATH study by "[u]sing the PATH longitudinal weights"). FDA's own data demonstrates that 99.5% of individuals believe that smoking cigarettes is harmful, and 91% believe that it is "very or extremely harmful." AR 27501, 27897-98; *see* AR 27901-02 (noting similar results in Gallup poll).[14]

The government also clings (at 24) to highly implausible results suggesting that 33% of adult smokers do not believe that "smoking is a proven cause of cancer," and that most respondents cannot identify cardiovascular disease as an illness they believe is caused by smoking. Again, these results fly in the face of FDA's own "nationally representative longitudinal dataset," AR 27897, which shows that 94% of adult respondents believe that smoking causes lung cancer in smokers, and that 88% of adult respondents believe that smoking causes heart disease in smokers, AR 27909-10; *see also* AR 27912-13 (since 2001, over 90% of respondents surveyed by the American Institute for Cancer Research list tobacco use as a risk factor for cancer).[15] The D.C. Circuit did not indulge the government's effort to ignore its own data in the first rulemaking, *R.J. Reynolds*, 696 F.3d at 1221, and this Court should not indulge it now.

iii. The government's more fundamental response (at 24-25) is that the *particular* risks of smoking addressed by the new warnings are not widely known. To begin, that's factually wrong, as a number of the warnings address risks that *are* widely known. Mot. 32; *see* AR 27915-16 (showing that between 82% and 93% of adult participants had knowledge related to eight of the specific risks in the

[14] Defendants do not suggest that weighing the data from different waves differently would have produced meaningfully different results. For example, the percentage of participants who believed smoking is very or extremely harmful to health was 91% in wave 1, 90% in wave 2, and 91% in wave 3. AR 27897-98.

[15] The government's heart disease statistic appears to derive from an unrepresentative, twenty-year-old study which encompassed only 249 smokers in two rural Ohio counties. AR 5114.

Rule's warnings).[16] But even setting that aside, the government simply has no substantial interest in delivering these narrow pieces of information. Mot. 33-34.

As Professor Klick explained—and as common sense dictates—once there is over 90% awareness that smoking is deadly, there is little reason to think that additional information (such as that it causes erectile dysfunction or cataracts) will be material to the public. AR 27934. And that is what his statistical analysis showed. Professor Klick found that acquiring knowledge of the risks addressed by the graphic warnings would have zero effect on smoking behavior, and would generally have no effect *even on people's assessment of the risks of smoking*. AR 27908.[17]

The government oddly dismisses this careful analysis as an "*ipse dixit*" (at 25), but offers literally nothing in its place other than the speculation of government counsel. The government admits (at 26) that it made no attempt to put any kind of value on the information the warnings contain; it also does not contest that it never mentioned these risks in a public relations campaign, despite running a number of such campaigns (Mot. 33-34); and it does not contest that its warnings will not change consumer behavior, instead acknowledging that it did not even study this question. Opp. 12 (admitting the second quantitative study did not "gauge" the effect of the warnings "on consumer behavior"). It is enough, from the government's perspective, to assert that the warnings "empower[] individuals to make fully informed choices about their health," Opp. 26—an assertion that could be made about *any* risk, however minor—even though consumers' actual "choices" will be unaffected by the warnings.

The government's assertion (at 21, 26) that it has an interest in allowing consumers to

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[16] The Rule objects to the use of PATH data on this point, arguing that the PATH questions do not precisely align with the proposed warnings. 85 Fed. Reg. at 15,655. That concern is overblown. For example, the PATH question that asks whether smoking causes "harm to fetuses (or unborn children) during pregnancy from second-hand smoke" corresponds very closely to the warning that "[s]moking during pregnancy stunts fetal growth." AR 27914, 27916. But any disjunction only undercuts Defendants' argument that they believe it is important for the public to know the specific risks in the graphic warnings; if they did, they would have included those risks in the PATH study. *See* AR 27908 ("It is concerning that the FDA did not even use the survey that was explicitly initiated to inform its tobacco regulations to examine the risks it now proposes to use in its warnings.").

[17] As with the rest of his analysis, Professor Klick provided a thorough explanation of his methods. *See* AR 27903-08 (explaining Professor Klick's fixed effects logistic regression model).

meaningfully evaluate whether to smoke is equally unsupported. To support that justification, the government would need to provide substantial evidence through its studies, at a minimum, of (i) whether smokers or prospective smokers regard the graphic warnings as providing information important and material to their decision whether to smoke, and (ii) whether the messages that they take from the graphic warnings are indisputably accurate and non-misleading. But as explained above (at 18 n.12), the government's studies focused on whether the graphic warnings conveyed "new information" of any sort, not *what* information consumers learned from them, whether that information was truthful and non-misleading, and whether it was important or material to consumers. In light of the abundant evidence that the warnings convey confusing and misleading messages to consumers about immaterial risks, *see supra* pp. 8-15, 20, the government's failure to even study these questions leaves its "interest" in informing consumer choice bereft of evidentiary support.

This brings into stark relief the radicalism of the government's position. In Defendants' view, not only are they entitled to rely on a purely informational interest, but they do not have to do *anything* to show that the information is actually important. They do not have to show that it has any value to the recipient; they do not have to show that it would affect the public's overall assessment of the problem; they do not even have to show that the government itself has taken the issue seriously in the past. All they have to show is that there is a piece of information that is not widely known. This is precisely the reductio ad absurdum that the D.C. Circuit panel worried about in *R.J. Reynolds*, and then-Judge Kavanaugh worried about in *American Meat Institute*. It is *always* possible to identify a more-granular fact that is not widely known. Accordingly, this rationale would potentially allow the government to justify compelled disclosures on any product and on any subject. This completely nullifies the "unjustified" safeguard of *Zauderer*.

(b) The Rule is also "unjustified" because it will not materially improve the public's understanding of the risks of smoking.

The government must also show that the compelled disclosures will actually remedy some existing problem. Mot. 34. It cannot do so here because, as discussed above, the Rule does not even purport to be addressing any real-world problem (as opposed to the academic interest of increasing

public understanding), and also because there can never be a legitimate government interest in mandating misleading disclosures. *Id.* But the Rule also suffers from another problem: the government has not shown that the Rule will help the public understand the risks of smoking. Mot. 34-39.

Defendants respond by relying almost exclusively on FDA's second quantitative study which shows—they claim—that the warnings outperformed the Surgeon General's warnings on several measures. *E.g.*, Opp. 33. This argument fails for several reasons.

First, the study was rife with methodological problems, as the peer reviewers showed. Mot. 14-16. The peer reviewers noted, among other things, that the study failed to use a representative sample (a limitation that was also noted by the U.S. Office of Management and Budget with respect to the first quantitative study, Mot. 49-50). The reviewers also observed that the two primary measures used by FDA (self-reported learning and new information) were novel, unproven, and unconvincing. Mot. 15. In short, as Professor Klick concluded, the analytical shortcomings of the studies rendered them unreliable. Mot. 14.

The government's response to all this (at 36) is a plea for deference. The government insists that it is free to simply reject the criticisms and plow ahead with the warnings anyway. But as noted above, *see supra* pp. 3-5, this demand for the Court to set aside its own judgment in favor of the agency's is misguided in the context of a First Amendment challenge. When free speech rights are at stake, FDA is not entitled to simply pick and choose among experts.[18]

Second, as the opening brief noted (at 38), outperforming the Surgeon General's warnings is

[18] The government also boasts that it pre-selected the "new information" and "self-reported learning" measures, thereby "leaving itself no wiggle room." Opp. 36. But the government claims only that it selected those measures before conducting the *second* quantitative study, not before it conducted *all* of its studies. Thus, when selecting these measures, it may already have had significant information about which measures would produce better results than others. Indeed, after its warnings did poorly on the believability metric in an earlier study, FDA chose to omit that metric from the second quantitative study, leaving a peer reviewer puzzled and critical. Mot. 36. In this respect, as in others, the government's approach smacks of what a peer reviewer called "*post hoc rationalization*." *See* AR 54052. The government's chosen measures instead appear designed to produce a pre-ordained outcome. Having decided to provide granular, immaterial information about smoking risks, it was hardly surprising that those warnings might score higher on "new information" and "self-reported learning" than the decades-old warnings about smoking's primary risks.

a meaningless metric. Defendants must show that the Rule *meaningfully* addresses the purported problem. It is not enough to show that the new warnings outperform 35-year-old, universally understood warnings that smokers have seen thousands or tens of thousands of times. The government complains (at 39) that "Plaintiffs fail to propose a different control," but it is the *government's* burden to show that the warnings comply with the First Amendment. As explained above, the government's testing was never designed to meet its actual burden: FDA did not test whether the graphic warnings conveyed factual and non-misleading information that would reduce smoking rates or improve public health, and relied on contrived "quantitative" measures of whether consumers supposedly learned *anything* new (irrespective of *what* that was or whether it was accurate).

Third, the study results actually show that the graphic warnings do *not* consistently beat the Surgeon General's warnings on two key measures. Most importantly, they did not consistently outperform the Surgeon General's warnings with respect to effect on health beliefs—the measure *of what respondents actually believe*, having seen the warnings, about the risks of smoking.[19] The government's response (at 38) is that, given the short time frame of the study, there was no reason to *expect* a good result on this measure. But this is an indictment of the study, rather than a defense of the measures on which FDA did rely (which do not capture whether the respondents actually learned or retained the information, Mot. 37). Again, it is up to the government to demonstrate that the warnings actually address a problem. *See R.J. Reynolds*, 696 F.3d at 1221 ("FDA cannot get around the First Amendment by pleading incompetence or futility."). If a longer study was needed to answer that question, Defendants were obligated to conduct a longer study (and they had since 2012, when the first graphic warnings rule was struck down, to do so).

Defendants also try to put a happy face on the health-beliefs results, suggesting that "the warnings performed remarkably well on that measure." Opp. 39. One wonders what performing

[19] In addition, most of FDA's warnings "were perceived as factual statistically significantly less than the Surgeon General's warnings." 85 Fed. Reg. at 15,660. The government brushes this off (at 38), suggesting that this poor outcome was due to the novelty of the warnings. But the government offers no evidence that the public's skepticism would actually fade over time.

remarkably poorly would look like. As the opening brief explained, and Defendants do not contest, out of the eleven warnings, five had *no* statistically significant effect on participants' knowledge (as compared to the Surgeon General's warnings) a little over two weeks after seeing them for the first time, and another five had a small effect one day after seeing them for the first time, and a much smaller effect two weeks later. Mot. 17. In other words, ten of the eleven warnings either did not affect health beliefs, or had a small effect that rapidly began to dissipate. And there is no reason to believe that the warnings would have *any* effect over an even slightly longer timeframe.

(c) The Rule is also "unduly burdensome."

The opening brief explained (at 39-41), and Defendants do not contest, that the Rule is highly burdensome. Indeed, the D.C. Circuit recently described *text-only* warnings that took a *smaller* portion of cigar packaging and would cost far *less* to implement as "obtrusive and expensive." *Cigar Ass'n*, 964 F.3d at 60, 62. And as the opening brief noted (at 44-45)—to no response from Defendants, who do not even cite these crucial cases—the Ninth and Seventh Circuits have invalidated far smaller warnings for being too burdensome. *Am. Beverage Ass'n v. City & Cnty. of San Francisco*, 916 F.3d 749, 754 (9th Cir. 2019) (en banc); *Entm't Software Ass'n v. Blagojevich*, 469 F.3d 641, 652 & n.13 (7th Cir. 2006).

i. This makes it all the more crucial for Defendants, at a minimum, to consider and test less-burdensome alternatives.[20] First, the government could have disseminated the additional information itself, through a public information campaign. Mot. 41. The availability of this alternative was fatal to

[20] While *Discount Tobacco* reached the opposite conclusion, its unpersuasive reasoning has been eviscerated by *NIFLA*. Fundamentally, *Discount Tobacco* treated *Zauderer* as a rational basis test, and *NIFLA* made it clear that this is wrong. *Compare Disc. Tobacco*, 674 F.3d at 554 (describing *Zauderer* as a "rational-basis standard"), *and id.* ("[T]o the extent that Plaintiffs argue that we must separately analyze whether the warnings are unduly burdensome, they are mistaken."), *with NIFLA*, 138 S. Ct. at 2376-77 (explaining that "under *Zauderer*, a disclosure requirement cannot be 'unjustified or unduly burdensome'" and the government "has the burden to prove that [the compelled statement] is neither unjustified nor unduly burdensome" (citation omitted)). Defendants also highlight (at 43) *Discount Tobacco*'s remarkable suggestion that graphic warnings *cannot* be unduly burdensome if they do not reduce the use of cigarettes. 674 F.3d at 567. (In other words, the Rule is not unduly burdensome precisely *because* it fails to achieve any real-world results.) This cannot be correct; by that logic, Defendants could commandeer cigarette packaging and advertising in their entirety, and drown out Plaintiffs' speech altogether, as long as the warnings remained ineffective at affecting actual behavior.

the government's position in *NIFLA*, 138 S. Ct. at 2376, and the same result should hold here.

The government's primary rebuttal (at 44) is that it already uses information campaigns. But so what? The relevant point, which the government does not contest, is that it has not run a campaign addressing *these risks*. Indeed, the fact that Defendants run so many public education campaigns and boast of their effectiveness only underscores why it was necessary to consider a public education campaign here. This is especially true because there is evidence in the record—which the government ignores—indicating that a public information campaign would work *better* (because it would allow FDA to convey more information, to update that information more rapidly, and to target specific audiences instead of relying on a "one-size-fits-all" message). Mot. 42.

The government also complains that public education campaigns "do not reach every person who looks at a package of cigarettes." Opp. 44 (internal quotation marks omitted). But the government does not have a sufficient interest in reaching *every* person who ever sees a pack of cigarettes. *Cf. Brown v. Entm't Merchants Ass'n*, 564 U.S. 786, 803 n.9 (2011) ("the government does not have a compelling interest in each marginal percentage point by which its goals are advanced"); *NIFLA*, 138 S. Ct. at 2376 (evidence that a government "advertising campaign" was ineffective was insufficient to justify "co-opt[ing] [private speakers] to deliver [the government's] message for it"). Instead, the question is whether a public information campaign would have *adequately* satisfied Defendants' objectives.

To be sure, Plaintiffs do not suggest that the government must *always* use a public information campaign instead of compelled disclosures. But if the government intends to impose a novel, unprecedented, and highly burdensome graphic warnings requirement, it must at least demonstrate that it could not achieve its goals through its own speech (instead of the compelled speech of others).

ii. In addition, FDA should have considered and tested less-intrusive versions of the graphic warnings—by changing their text, location, size, or some combination thereof, and/or using solely text. Mot. 43.[21] The government, however, tested *none* of these options, relying on generic conclusions

[21] Defendants cite (at 42) the plurality opinion in *Burson v. Freeman*, but that opinion suggests only that *marginal* policy changes (such as whether an individual could be undisturbed before entering a polling place for an additional fifteen seconds) are not constitutionally significant. 504 U.S. 191, 210

that bigger is better, and that graphic warnings are better than text-only warnings. Opp. 42-43, 45. This logic would equally justify warnings that take up 90 rather than 50 percent of cigarette packaging, and would also justify including grotesque photorealistic images on every product warning label.

The government's failure to carry its burden is especially stark in light of the record evidence—which the government ignores—suggesting that less-restrictive alternatives would have worked equally well. For example, textual warnings have worked well before, and FDA does not explain why they could not work well again. Mot. 43. Moreover, Dr. Iyengar performed the analysis the government refused to perform and actually conducted a survey comparing FDA's warnings to several less-restrictive alternatives. She found very few statistically significant differences in the amount of "new information" conveyed or in respondents' beliefs about smoking risks. *Id.* at 43-44. And her conclusions are reinforced by other studies discussed in the record. *Id.* at 44. Having been so thoroughly put on notice of the likely efficacy of several readily available less-restrictive alternatives—indeed, one of the Plaintiffs expressly urged FDA to test several of these alternatives as early as 2018, Mot. 44—the government had no conceivable excuse for burying its head in the sand.

In the end, the government tries (at 42, 44) to hide behind Congress's judgment. Indeed, the Rule admits that FDA did not test any alternative that was not contemplated by the TCA. 85 Fed. Reg. at 15,650-51. But as shown above, the warnings are unduly burdensome under governing First Amendment doctrine, and Congress cannot relieve Defendants of their constitutional obligations. Moreover, as the D.C. Circuit noted in rejecting a similar argument in *R.J. Reynolds*, "deference is only warranted where Congress 'base[s] its conclusions upon substantial evidence,' … and Congress's predictive judgments are not 'insulated from meaningful judicial review.'" 696 F.3d at 1221 n.15 (quoting *Turner Broad. Sys., Inc. v. FCC*, 520 U.S. 180, 196 (1997), and *Turner Broad. Sys., Inc. v. FCC*, 512 U.S. 622, 666 (1994)).[22] Here, too, Defendants have not pointed to any *evidence* considered by Congress

(1992) (plurality opinion). Defendants cite no similar authority from the compelled-speech context, and in any event the proposed changes to the warnings here would be significant rather than marginal.

[22] Defendants rely (at 42) on *Schirmer v. Edwards*, 2 F.3d 117 (5th Cir. 1993), which is easily distinguishable. In *Schirmer*, the state legislature expanded a regulation (in degree, rather than in kind)

that would suggest that less-restrictive versions of the warnings would not be sufficiently effective.

3. The *Central Hudson* standard does not apply (and the Rule would fail it in any event).

Plaintiffs have already explained that strict scrutiny, rather than intermediate scrutiny, is the appropriate standard for compelled disclosures that are not "purely factual and uncontroversial" or are otherwise ineligible for *Zauderer* review. *See* Mot. 20-21, 45. But even assuming that *Central Hudson* were the correct standard for compelled commercial speech that falls outside of *Zauderer*, the Rule fails under the *Central Hudson* framework for the same reasons it fails under *Zauderer*.

First, the government's asserted interest in the Rule is not substantial. The government has no substantial interest in providing consumers misleading, inaccurate, and emotionally charged information that will have no real-world impact on consumer behavior or on public health. *See R.J. Reynolds*, 696 F.3d at 1221 (a "purely informational" interest in "'effectively communicating' the health risks of smoking is . . . not an independent interest capable of sustaining the Rule"); *Int'l Dairy Foods Ass'n v. Amestoy*, 92 F.3d 67, 73 (2d Cir. 1996) ("'strong consumer interest and the public's "right to know"' . . . are insufficient"). Defendants' authorities are not to the contrary. Indeed, the government's interest in each case was in the real-world impact of the compelled disclosures or speech restrictions. *See Citizens United*, 558 U.S. at 368, 371 ("avoid[ing] confusion" and enabling citizens "to react to the speech of corporate entities in a proper way"); *Bd. of Trs. of State Univ. of N.Y. v. Fox*, 492 U.S. 469, 475 (1989) ("promoting an educational . . . atmosphere on [public college] campuses, promoting safety and security, preventing commercial exploitation of students, and preserving residential tranquility"); *Cent. Hudson*, 447 U.S. at 568-69 ("conserving energy" and increasing the likelihood of "fair and efficient" electricity rates); *Kansas v. United States*, 16 F.3d 436, 443 (D.C. Cir. 1994) ("ensuring adequate facilities for interstate air travel"); *Cramer v. Skinner*, 931 F.2d 1020, 1034 (5th Cir. 1991) ("resolving [a] dispute between [cities]" which "had long hindered efforts to improve airline service").

Second, the government has failed to show that the Rule will directly advance its asserted

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after the initial version did not work. *Id.* at 122. Here, Defendants have not tried smaller or differently-placed graphic warnings (and text warnings have been shown to work *well* rather than badly, Mot. 43).

interest in informing the public to "a material degree." *Edenfield*, 507 at 770-71. As discussed, the public already knows the risks of smoking, *see supra* pp. 18-19; the warnings will not meaningfully affect their knowledge of the risks, *see supra* pp. 21-24; and the warnings will mislead, confuse, and frighten consumers with inaccurate and emotionally charged messages. *See supra* pp. 8-15.

Third, the government cannot demonstrate that the Rule is "not more extensive than is necessary to serve that interest." *Cent. Hudson*, 447 U.S. at 566. As explained above, the government failed even to consider or test various less-restrictive alternatives, despite record evidence suggesting they would work equally well or better. *See supra* pp. 24-27.

4. The Rule fails strict scrutiny.

As noted in the opening brief (at 47), the Rule does not come close to satisfying strict scrutiny. Indeed, FDA did not claim in the Rule itself that the warnings could survive strict scrutiny. 85 Fed. Reg. at 15,649. The government half-heartedly asserts this now, but its argument is insubstantial.

Lacking doctrinal support, the government proceeds (at 47) mainly by erecting a hypothetical about mandating warnings for a *new* product similar to cigarettes. But if the situation were truly similar—that is, the public was universally aware that the new product was harmful, FDA conceded that the warnings would have no real-life impact, FDA declined to consider less-burdensome alternatives, and so on—the graphic warnings would be equally unlawful for the new product.

The bottom line is that the government cannot demonstrate that its purely informational interest is "compelling," let alone that its ineffective and burdensome warnings are "narrowly tailored" to achieving it. *See Reed v. Town of Gilbert*, 576 U.S. 155, 171 (2015); *Entm't Software*, 469 F.3d at 652 (concluding a four-square inch sticker "literally fail[ed] to be narrowly tailored").

B. The TCA's Graphic-Warnings Requirement Also Violates The First Amendment.

As noted in the opening brief (at 47-48), the TCA's graphic warnings provision mandates that FDA issue extraordinarily burdensome warnings with a facially unconstitutional purpose—namely, promulgating the government's anti-smoking message—and an inevitably unconstitutional effect.

The government responds (at 48-49) primarily by invoking the high standard for facial

challenges to statutes. But it does not explain why the standard is not met here. In particular, it does not even attempt to describe how a rule could comply with the TCA *without* transforming every cigarette package and advertisement into an ideological "mini-billboard" for the government. *R.J. Reynolds,* 696 F.3d at 1212 (quoting FDA, Tobacco Strategy Announcement (Nov. 10, 2010)). Nor does it explain how the warnings could advance a valid government interest that could not be advanced through less speech-burdensome methods. That failure is unsurprising; to date, FDA has had two shots at crafting a constitutional rule, and it has failed both times. This demonstrates that—contrary to the expectations of the *Discount Tobacco* panel, 675 F.3d at 559—a constitutional graphic warnings rule cannot be issued. If Defendants believe that they can fix the constitutional flaws in the current rule, they should have identified how they would do so.[23]

C. The Rule Violates The APA.

1. FDA acted arbitrarily and capriciously.

The opening brief identified (at 48-52) five ways in which the government acted arbitrarily and capriciously. The government only attempts to respond to one, and is not persuasive even there.

a. The sole criticism the government attempts to rebut is Plaintiffs' criticism of its cost-benefit analysis. It asserts (at 50) that it was not required by the TCA to conduct a cost-benefit analysis, that it did so only to comply with certain executive orders, and that the flaws in the analysis are therefore irrelevant. This response misses the point: *if* the government chooses to conduct a cost-benefit analysis

[23] The government suggests in a citation-free footnote (at 43 n.25) that *Discount Tobacco* has preclusive effect against Reynolds. Such a cursory argument is forfeited. *See United States v. Olguin*, 643 F.3d 384, 399 (5th Cir. 2011). It is also pointless, given that the other plaintiffs' claims unquestionably are *not* precluded. And *Discount Tobacco* has no preclusive effect even as to Reynolds. This is true in light of intervening factual developments (namely, the government's repeated failures to issue a constitutional graphic warnings rule) and an intervening change in the law (namely, *NIFLA*'s rejection of *Discount Tobacco*'s approach to *Zauderer*, *see supra* note 20). *See Whole Woman's Health v. Hellerstedt*, 136 S. Ct. 2292, 2305-06 (2016); 18 Wright & Miller, Federal Practice & Procedure § 4415 (3d ed.). In reality, it is *the government* that is precluded from contesting the holding of *R.J. Reynolds* that a "purely informational" interest cannot "stand on its own." 696 F.3d at 1221; *see Nations v. Sun Oil Co. (Delaware)*, 695 F.2d 933, 938 (5th Cir. 1983) (setting out the elements of issue preclusion); *EEOC v. Am. Airlines, Inc.*, 48 F.3d 164, 171-72 (5th Cir. 1995) (applying issue preclusion against federal agency).

(for whatever reason) and incorporates it into the Rule, as it did here, the flaws in the cost-benefit analysis can render the Rule arbitrary and capricious. *See, e.g., Idaho Conservation League v. Wheeler*, 930 F.3d 494, 507 (D.C. Cir. 2019); *Council of Parent Attorneys & Advocates, Inc. v. DeVos*, 365 F. Supp. 3d 28, 54 n.11 (D.D.C. 2019) (rejecting a virtually identical argument by another agency), *appeal dismissed*, No. 19-5137, 2019 WL 4565514 (D.C. Cir. Sept. 18, 2019).[24]

Here, the government's failure to quantify the Rule's benefits was quintessentially arbitrary and capricious—especially given that the costs of the Rule (constitutional, financial, and otherwise) are so great. For example, even to the very limited extent the government considered alternative approaches (such as only mandating nine warnings), its failure to assess the benefits of the Rule left it entirely unable to explain why it picked one (more costly) alternative over the other. Mot. 51.

More generally, the government's cramped assessment of the Rule's costs and benefits reflects its broader failure to articulate a satisfactory explanation for its action. *See State Farm*, 463 U.S. at 43. In particular, the government failed to consider whether the Rule would reduce smoking. *See, e.g.*, AR 27529 (identifying this as a "crucial defect" from an APA standpoint); AR 36105-06.

This defect by itself is enough to invalidate the Rule. In *Cigar Association*, the D.C. Circuit recently struck down mandatory health warnings for cigars and pipe tobacco, relying primarily on an express statutory provision requiring FDA to take into account the regulation's likely impact on the prevalence of smoking. 964 F.3d at 61-65. But in the course of the analysis, the court noted that its conclusion "accords with common sense," given the obtrusiveness of the warnings, as well their cost and their effect on the speech interests of manufacturers. *Id.* at 62. "When requiring a product to bear such obtrusive and expensive health warnings, it is difficult to imagine a more important 'aspect of the problem,' than whether the warnings will actually affect product usage." *Id.* (quoting *State Farm*, 463 U.S. at 43). Here, as noted above, the warnings are far *more* intrusive than the warnings at issue in

[24] *Air Transport Association of America v. FAA*, 169 F.3d 1 (1999), is not to the contrary. It simply held that private entities cannot enforce the obligations created by EO 12,893, which concerns cost-benefit analyses. *Id.* at 8-9. *Air Transport Association* does nothing to undercut the general principle that, if an agency includes a cost-benefit analysis in its Rule, the flaws in that analysis can infect the Rule.

Cigar Association. Accordingly, FDA failed to consider an important element of the problem, and that means the Rule must be struck down as arbitrary and capricious under *State Farm*, 463 U.S. at 43.

b. As for the other four criticisms, Defendants assume (at 50) that they are simply variants on Plaintiffs' First Amendment arguments. Not so. Indeed, two of the four arguments have no direct counterpart in the First Amendment context. First, FDA is obligated to respond meaningfully to the comments it received. But as the opening brief notes, and the government does not contest, FDA provided *no* meaningful response to the criticism of its qualitative studies. Mot. 51. Second, FDA acted arbitrarily and capriciously in its handling of the peer review report. It failed to adequately address the reviewers' fundamental criticisms; instead, it improperly claimed that their comments were largely positive and called only for cosmetic, non-substantive changes. Mot. 14, 52. And FDA deepened the error by failing to give the public an opportunity to comment on the peer review report, or its handling of it. *Id.* at 52; *see Prometheus Radio Project v. FCC*, 652 F.3d 431, 447, 450 (3d Cir. 2011). Once again, the government offers no direct response.[25]

As for the remaining two criticisms, the APA requires the agency to (1) support its actions with adequate evidence and (2) consider alternative regulatory approaches.[26] FDA failed in these obligations by (1) relying on studies which suffered from significant methodological problems (including problems noted by OMB) and (2) largely failing to consider alternatives and then entirely failing to explain why it did not adopt the few alternatives it did consider. Mot. 49-51.

2. FDA failed to provide meaningful notice and opportunity to comment.

a. Likewise, FDA failed to provide meaningful notice and opportunity to comment with respect to two key categories of information.

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[25] Elsewhere in the brief, the government claims (at 36 n.23) to have addressed one criticism from one peer reviewer; but it never attempts to defend its overall handling of the peer review report.

[26] Defendants raise the issue (at 17 n.8) whether the proper test is "substantial evidence" or "arbitrary [and] capricious." There is no need to address this issue, however, because the Fifth Circuit has "acknowledged that when applied to informal rule making, the two criteria tend to converge." *Superior Oil Co. v. FERC*, 563 F.2d 191, 199 (5th Cir. 1977).

First, FDA withheld the study reports for its qualitative studies when it issued the proposed rule. *See* Mot. 53-54. Defendants seem to concede (at 56 & n.32) that they were required to give the public notice of these study reports.[27] They argue that they cured this error by releasing the study reports later, and giving the public fifteen days to comment. But they overlook the multiple cases cited in the opening brief, all of which stand for the proposition that fifteen days is not an adequate comment period. Mot. 55.[28] This is especially true in light of the fact that the reports are complex, multi-hundred-page documents which implicate many of the key issues concerning the Rule. *See* AR 23281-862. And it is nothing short of brazen for the government to claim (at 57) that it was forced into allowing only a fifteen-day comment period by a court-imposed deadline. In reality, the problem was entirely of the agency's own making. FDA could (and should) have simply released these reports—which were all dated over a year before the proposed rule was published—alongside the proposed rule. *See* Opp. 10 (trumpeting FDA's careful "years-long process" of developing the Rule).

Second, Defendants failed to provide the underlying data for all of its studies until last month (when they served that information on Plaintiffs as part of the administrative record). *See* Mot. 54. This is another category of information that FDA was obligated to release to the public during the rulemaking process. *See Owner-Operator Indep. Drivers Ass'n, Inc. v. Fed. Motor Carrier Safety Admin.*, 494 F.3d 188, 199 (D.C. Cir. 2007); *United States v. Nova Scotia Food Prods. Corp.*, 568 F.2d 240, 252 (2d Cir. 1977); *Am. Radio Relay League, Inc. v. FCC*, 524 F.3d 227, 240 (D.C. Cir. 2008).

The cases on which FDA relies are inapposite. In *Texas Office*, the plaintiffs complained about a non-mandatory *second* notice-and-comment period, and did not dispute that the first round "met the

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[27] The government maintains that it "did not rely on these studies as part of the rulemaking," but then promptly acknowledges that they were "used to inform further research," namely the quantitative studies. Opp. 52-53 (internal quotation marks omitted); *see id.* at 11-12.

[28] The cases cited by Defendants only undermine their position further. *Petry v. Block* stands for the proposition that generally speaking *sixty days* is the reasonable minimum time to comment on rules "based on scientific or technical data." 737 F.2d 1193, 1201 (D.C. Cir. 1984); *see* Mot. 55. And in *Phillips Petroleum Co. v. EPA*, the court concluded that plaintiffs were not entitled to a 45-day extension of a 30-day comment period when plaintiffs were "given a full and fair opportunity to comment" and benefited from other procedural protections. 803 F.2d 545, 559 (10th Cir. 1986).

APA requirements." 265 F.3d at 326. And in *Chemical Manufacturers Association v. EPA*, the agency updated and expanded its data source in response to industry criticism (rather than shielding itself from criticism by failing to disclose data). 870 F.2d 177, 202 (5th Cir. 1989).[29]

Notably, in a "Memo to File" that was included in the administrative record, FDA candidly explained why it did not disclose the data. It expressed concern that doing so would "allow third party attempts to analyze the data in different and potentially selective, biased or misleading ways other than what FDA pre-specified in the statistical analysis plan." AR 236863.2. But the very premise of notice-and-comment rulemaking is that the agency's pre-conceived analytical methods ought to be subject to challenge and criticism. Distrust of the public is no reason to bypass that mechanism.

b. The government is wrong to suggest (at 58-59) that these violations were harmless. The bar for showing APA prejudice is low, and Plaintiffs easily clear it. *See Sierra Club v. U.S. Fish & Wildlife Serv.*, 245 F.3d 434, 444 (5th Cir. 2001) ("Agency mistakes constitute harmless error only where they 'clearly had no bearing on the procedure used or the substance of decision reached.'" (citation omitted)); *U.S. Steel Corp. v. EPA*, 595 F.2d 207, 215 (5th Cir. 1979); *Owner-Operator*, 494 F.3d at 202-03; *Texas v. EPA*, 389 F. Supp. 3d 497, 506 (S.D. Tex. 2019). Here, Plaintiffs were prejudiced by FDA's failure to comply with the APA's requirements as to both categories of information.

As to the qualitative study reports: If Plaintiffs had additional time to comment on those reports, Reynolds's survey expert could have included additional questions in her survey based on what those reports revealed regarding what participants found confusing and misleading about the proposed warnings. *See* Mot. 56. For example, she could have assessed whether using "can cause" rather than "causes" increases believability and decreases confusion. Defendants insist (at 61) that such results would be immaterial, because they would have "'nothing to do with the actual factual accuracy' of the warnings." Yet Defendants themselves defend the warnings (at 37) as being "not

[29] *Corrosion Proof Fittings* and *Aqua Slide* also do not support Defendants' argument. In both, the court *invalidated* a regulation for lack of substantial evidence because the agency failed to timely release the data on which it had relied. *Corrosion Proof Fittings v. EPA*, 947 F.2d 1201, 1212 (5th Cir. 1991); *Aqua Slide 'N' Dive Corp. v. Consumer Prod. Safety Comm'n*, 569 F.2d 831, 842 (5th Cir. 1978). Neither of those decisions actually reached a holding as to the notice requirement of 5 U.S.C. § 553.

confusing" based on metrics like "perceived understandability." Accordingly, these additional survey questions could have further demonstrated that the warnings are confusing and misleading (in violation of the First Amendment), and that it would be arbitrary and capricious to choose phrasing that increases confusion. The survey could have also replicated the issues revealed by the qualitative studies on a larger scale, preventing the government from dismissing them (at 32) as stray comments.

More generally, Plaintiffs could have used the qualitative studies to reinforce their argument that the warnings were misleading and provoked negative emotions. Mot. 26-27. The government complains that Plaintiffs (at 60) have not explained precisely what they would say. In reality, Plaintiffs have identified—and collated into an appendix, which they attached to their motion—a significant body of evidence from the qualitative studies that reinforces their position. *See* Mot. 28 (relying on the appendix). Plaintiffs could and would have used all of this information in their comment as well. In other words, Plaintiffs have thoroughly demonstrated how they would have been able to mount an even more "credible challenge" to the Rule based on the qualitative studies if they had been afforded such an opportunity. *See Owner-Operator*, 494 F.3d at 202-03; *Texas v. EPA*, 389 F. Supp. 3d at 506.

Plaintiffs also suffered prejudice from Defendants' failure to release the underlying data for all of the studies. Needless to say, prior to receiving the underlying data (which just happened recently), Plaintiffs could not specify precisely what they could have done with it. Having now received the data, Plaintiffs have learned that it provides yet more evidence that the warnings are confusing, misleading, and designed to provoke negative emotional reactions. This evidence is compiled in another appendix, which is attached to this brief. *See* Second App. In addition, if Plaintiffs had received the data in time, it would have been useful in assessing various issues that the government has still failed to adequately explain, such as why it choose to create warnings for some diseases while ignoring other diseases that are more serious and more common. *See* Mot. 54.[30]

[30] Defendants insist (at 59) that they have explained this issue, but their only citation is to the *proposed* rule. *See Cigar Ass'n*, 964 F.3d at 64 (concluding the APA precludes the court from upholding a rule based on reasoning that appears only in the proposed rule). And even the proposed rule includes only the generic statement that FDA considered whether to revise "the TCA statements to focus on negative health effects that are less-known or less understood." 84 Fed. Reg. at 42,767.

Finally, while the government boasts (at 59) that the peer reviewers did not raise concerns about the information they were provided, in reality they did. *See* AR 54058-59 (Reviewer 2) (suggesting that additional information be provided for Study 1, including "how revised warning statements were selected" and "more information about measurement[s]"); AR 54064 ("no justification for the selection of stimuli for Study 2"); AR 54084 (Reviewer 4) (additional information was needed for Study 1, including "formative work that went into development of the new warning labels; . . . choice of vendor (given the important limitations inherent in the non-representative sample); and validity of key measures used"); AR 54088 ("The specific procedures that went into development of the new text warnings and images were not described in detail [in Study 2]; more information on formative work would improve the presentation of the report. Additional information that links measures to their origin in the literature and provides some evidence of validity is needed.").

The government's bottom-line position on harmless error (at 59, 61) is that it would not have changed the Rule based on the additional insights the disclosed information would have yielded. But this is not the test; the "likelihood that the result would have been different" is only one of numerous factors that courts consider in assessing whether an agency error is harmless. *See City of Arlington v. FCC*, 668 F.3d 229, 243-44 (5th Cir. 2012), *aff'd*, 569 U.S. 290 (2013). In any event, Plaintiffs' analysis of the additional information might well have justified a rule that was different in at least some respect. *See Chamber of Commerce of U.S. v. SEC*, 443 F.3d 890, 904 (D.C. Cir. 2006) (error was not harmless where there was "[un]certainty" as to whether a party's "comments would have had some effect").

The government may be right that *in fact* FDA would have ignored any further comments and adhered to its predetermined outcome, engaging in whatever additional "post hoc rationalization[s]" were necessary. *See* AR 54052. But FDA's intransigence cannot shield its errors from judicial review.

D. The Rule Violates The TCA.

The text, structure, and purpose of the TCA demonstrate that FDA can adjust the text of the warning statements only *after* promulgating a graphic warnings rule. Mot. 56-58. The government complains (at 64) that this argument is atextual, but it is rooted squarely in the statute's use of "accompany" in Section 201(a), as well as the inclusion of the term "color graphics" in Section 202(b).

The TCA, by its plain text, also does not authorize FDA to change the *number* of warnings. Once again, FDA complains (at 65) that this argument is atextual, criticizing Plaintiffs for failing to point to statutory language that prohibits FDA from changing the number of warnings. But it is up to Defendants to identify statutory language that *allows* FDA to change the number of warnings (as opposed to their format, type size, color graphics, or text), and there is no such language in § 1333.[31]

FDA instead refers to 15 U.S.C. § 1334(a), which mentions "additional or different" statements that FDA may require "on any cigarette package by a regulation." FDA contends this language proves Congress intended to allow FDA to increase the number of graphic warning statements. But the language need not refer to additional graphic warnings; it could also refer, for example, to disclosures that FDA can require under 15 U.S.C. § 1333(e).

Unsurprisingly, the government ends its statutory argument with a plea for *Chevron* deference. This argument also fails, because FDA's approach is unambiguously foreclosed by the statute's text. *See Forrest Gen. Hosp. v. Azar*, 926 F.3d 221, 228 (5th Cir. 2019).[32]

E. The Rule Should be Struck Down in Its Entirety.

Defendants argue that any unlawful portions of the Rule should be severed. This is mistaken.[33]

For starters, Defendants assume that only a portion of the Rule (specifically, the mandated

[31] The government is also inconsistent in its approach to the phrase "label requirements" in Section 1333(d)[2]. If it believes that the number of warnings is merely a "label requirement" subject to revision, then it should take the same view about their size and placement. This further undercuts its attempt to hide behind Congress's judgment for First Amendment purposes, and further demonstrates why it was required to consider alternatives for APA purposes. *See supra* pp. 26-27, 31.

[32] And even if the statute were ambiguous, FDA would receive no deference under *Chevron* step two as to its authority to change the textual warnings before issuing a graphic warnings rule, because it construed the statute as "an unambiguous expression of the Congress's intent" and believed its authority was "plain from the statute's face." *See Peter Pan Bus Lines, Inc. v. Fed. Motor Carrier Safety Admin.*, 471 F.3d 1350, 1353-54 (D.C. Cir. 2006). FDA expressly opined that the statutory text "plainly contemplates that FDA may adjust the 'text' of the label requirements . . . precisely as this final rule does." 85 Fed. Reg. at 15,642. FDA also asserted that "nothing in the language of [TCA] . . . requires the Agency to first issue warnings with the [TCA] statements, and then wait 15 months or more for such warnings to be implemented, before" FDA could revise the warning statements. *Id.* at 15,643.

[33] Defendants also obliquely criticize Plaintiffs (at 68) for discussing severability only in a footnote. But Plaintiffs were not obligated to discuss severability at all, given that Defendants had yet to file a brief seeking severance. *See Hoyt v. Lane Constr. Corp.*, 927 F.3d 287, 296 n.2 (5th Cir. 2019).

images, rather than the text) would be invalidated. Opp. 67-68. But Plaintiffs' arguments demonstrate that the Rule is invalid in its totality. For example, the asserted interest supporting the Rule—namely, providing information for information's sake, with no real-world effect—is invalid, and therefore, the *entire* Rule is invalid. *See supra* pp. 16-18. Similarly, the *entire* Rule is unduly burdensome due to FDA's failure to consider less-burdensome alternatives. *See supra* pp. 24-27. In addition, Plaintiffs have shown that *both* the images and the text are impermissibly misleading. *See supra* pp. 8-15. And Plaintiffs' APA and TCA arguments also are not limited to the graphic portion of the warnings. *See supra* pp. 29-36.

Moreover, even if Defendants were right that only the images are legally problematic, the TCA *prohibits* the images from being separated from the textual warning statements. The TCA expressly states that the graphic warnings must "accompany" the textual warnings provided for in the TCA. 15 U.S.C. § 1333(d)[1]. As such, Congress has expressly decided that a graphic warnings rule must involve *both* graphics and text, so those two portions of the Rule cannot be severed from each other.

The TCA's severability provision is not to the contrary. First, Congress's general preference for severability expressed in the provision is overcome here by its specific intention that graphic images and the textual warnings provided for in the TCA must accompany each other. *See Navarro-Miranda v. Ashcroft*, 330 F.3d 672, 676 (5th Cir. 2003) ("As a fundamental rule of statutory interpretation, specific provisions trump general provisions."). Second, the two provisions can be, and thus should be, read harmoniously. *See United States v. Elrawy*, 448 F.3d 309, 315 (5th Cir. 2006). The severability provision says that if one "provision" of a regulation is invalid, the remainder of the regulation should generally remain in effect. 21 U.S.C. § 387 (note). But here, the textual and graphic warnings are part of the same provision of the Rule: Section 1141.10(a), entitled "Required warnings."

In short, FDA's severability argument need only be considered if the Court chooses to invalidate some warnings but leaves others in effect. But even then it would remain necessary to ask whether the regulation would "function sensibly" in the absence of the invalidated portion. *MD/DC/DE Broadcasters Ass'n v. FCC*, 253 F.3d 732, 734 (D.C. Cir. 2001); *see also* Opp. 69 (conceding this test applies); *Chamber of Commerce v. U.S. Dep't of Labor*, 885 F.3d 360, 388 (5th Cir. 2018). *R.J. Reynolds* struck down the first graphic warnings rule in its entirety, despite the TCA's severability

provision, 696 F.3d at 1222, and the same result is compelled here.[34] There is no basis for saying the Rule would function sensibly if some warnings were invalidated, especially since Defendants do not know which warnings those would be. The government is essentially asserting that *any* subset of its warnings is a sensible replacement for the Surgeon General's warnings—including, for example, *solely* the erectile dysfunction warning. That is the opposite of sensible.

There is even less reason to think that the textual warnings could sensibly function on their own. After all, the second quantitative study, on which the government very heavily relies, did not test the textual warnings separately from the images. *See* AR 39686. What is more, the Rule provides no information as to what text-only warnings would look like (for example, whether the size of the text would remain the same even though the graphics were eliminated).

F. Nationwide Relief Is Appropriate.

The government offers a lengthy critique of "nationwide relief that would run to the benefit of those who are not parties to this case," Opp. 71,[35] but its argument is foreclosed by precedent. It is black letter law that vacatur—which deprives a regulation of all force—is the standard remedy for an unlawful regulation. *See, e.g.*, *Franciscan All., Inc. v. Azar*, 414 F. Supp. 3d 928, 944-46 (N.D. Tex. 2019); *Nat'l Mining Ass'n v. U.S. Army Corps of Eng'rs*, 145 F.3d 1399, 1409 (D.C. Cir. 1998); *see also Chamber of Commerce*, 885 F.3d at 388. The government focuses instead on the supposed impropriety of nationwide injunctions. But even there, the Fifth Circuit has made clear that nationwide injunctions are permissible and may even be required in APA cases. *Texas v. United States*, 809 F.3d 134, 188 & n.211 (5th Cir. 2015). Notably, this Court has already stayed the effective date of the Rule (at the parties' invitation). Having previously asked this Court to grant relief that runs to nonparties, the

[34] Nor does the Rule's severability provision counsel a different outcome. As the D.C. Circuit explained, "the ultimate determination of severability will rarely turn on the presence or absence of [a severability clause in a regulation]." *Community for Creative Non-Violence v. Turner*, 893 F.2d 1387, 1394 (D.C. Cir. 1990) (internal quotation marks omitted).

[35] Despite the government's use of the term "nationwide relief," the only actual disagreement here is whether the Court's remedy would protect parties other than Plaintiffs. Opp. 71. There is no question that it would have to fully protect the Plaintiffs, some of whom operate nationwide.

government can hardly argue now that such relief is beyond the Court's authority.

The government is also wrong that nationwide relief should be denied because another lawsuit has been filed challenging the Rule. Courts routinely vacate unlawful rules, and enter nationwide injunctions, in cases that are being litigated in multiple fora. *See, e.g.*, *Texas v. United States*, No. 7:16-CV-00054-O, 2016 WL 7852331, at *2-3 & n.2 (N.D. Tex. Oct. 18, 2016); *Franciscan All., Inc. v. Azar*, 414 F. Supp. 3d at 944-46; *Franciscan All., Inc. v. Burwell*, 227 F. Supp. 3d 660, 695 (N.D. Tex. 2016).

G. No Changes to Cigarette Packages or Advertising May Take Effect Until 15 Months After The Issuance of a Valid Rule.

The government agrees (at 70) that, if the Rule is invalidated in its entirety, the related requirements should not take effect until 15 months after the issuance of a *valid* Rule. Accordingly, Defendants have no basis for objecting to an order that would clarify this. Indeed, this Court has already adopted this approach; in its scheduling order, it postponed not only the effective date of the rule, but also "[a]ny obligation to comply with a deadline tied to the effective date of the rule." Order at 2. Thus, if the Court invalidates the Rule, as it should, it should also order that textual warnings and related requirements cannot take effect until fifteen months after FDA issues a lawful Rule.

II. PLAINTIFFS ARE ALSO ENTITLED TO A PRELIMINARY INJUNCTION.

Defendants suggest (at 73-74) that the preliminary injunction motion is now superfluous because it is being briefed on the same schedule as the summary judgment motions. This is incorrect. To be sure, the Court *could* simply resolve the parties' cross-motions for summary judgment, bypassing a ruling on the preliminary injunction motion. But the Court could also conclude that it is possible to resolve the preliminary injunction motion more expeditiously, inasmuch as it would not require a full assessment of the merits. Doing so would protect Plaintiffs from irreparable harm.

Defendants are right to concede (at 74-75) that the Manufacturer Plaintiffs will incur significant expenses in preparation for complying with the Rule. They are wrong, however, to suggest that these costs will not be incurred until after the Court resolves the summary-judgment motions. Plaintiffs' uncontroverted declarations demonstrate that such expenses *are already being incurred*. *See* Declaration of Lamar W. Huckabee (ECF No. 34-5) ("Huckabee Decl.") ¶ 10 ("process has been

underway"); *id.* ¶ 11 ("costs have already been incurred"); Declaration of Kim Reed (ECF No. 34-6) ("Reed Decl.") ¶ 10 ("costs have already been incurred"); Declaration of Francis G. Wall (ECF No. 34-7) ("Wall Decl.") ¶ 7 ("the Rule imposes severe, immediate, and continuing economic costs").[36]

As this Court has explained, these losses are irreparable because they cannot be recouped. *See* May 8, 2020 Order at 1-2; *see also, e.g., Texas v. EPA*, 829 F.3d 405, 433-34 (5th Cir. 2016). The irreparable harm prong of the analysis thus favors the Plaintiffs.

As to the remainder of the analysis, Defendants largely ignore Plaintiffs' arguments. As Plaintiffs explained (at 64-65): (1) protecting First Amendment rights is always in the public interest; (2) FDA has shown no urgency in promulgating the Rule; (3) delaying the Rule will not cause any cigarettes to be sold without adequate warnings; and (4) FDA has failed to quantify any tangible benefit of the Rule, meaning that a delay of the Rule will not significantly impact the public interest.

Instead of responding to these points, Defendants seek (at 75) to reframe this lawsuit as an effort to resist the disclosure of information about cigarettes. In reality, this lawsuit seeks to vindicate basic First Amendment principles. Indeed, one might have expected the government to be more circumspect in its rhetoric given that the previous version of the graphic warnings rule was struck down as unconstitutional. The new Rule is equally flawed, and should meet the same fate.

CONCLUSION

For those reasons, the Court should grant Plaintiffs' motion for summary judgment and a preliminary injunction, order the relief sought in those motions, Mot. 65, and deny Defendants' cross-motion for summary judgment.

[36] Moreover, additional costs would be incurred during this litigation. *See* Huckabee Decl. ¶ 12 (design work "must begin a few months after the Rule is published"); Reed Decl. ¶ 11 (design work "must begin shortly after the final Rule is published"); *id.* ¶ 18 ("must continue with these steps now"); Wall Decl. ¶ 11 ("would have to begin designing new packaging and developing its new manufacturing process immediately"). And even more costs are around the corner. For example, the Manufacturer Plaintiffs will have to engrave printing cylinders in January 2021 or earlier, and acquire printing cylinder bases and tools before then. Huckabee Decl. ¶ 11; Reed Decl. ¶¶ 10, 18; Wall Decl. ¶ 19.

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on August 14, 2020, a true and correct copy of the foregoing was electronically filed with the clerk of court for the U.S. District Court for the Eastern District of Texas, using the CM/ECF system, which will send a notice of electronic filing to all counsel of record.

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